

Appl. No.: 10/768,762
Amdt. dated: 02/23/2007
Reply to Office action of: 11/03/2006

REMARKS / ARGUMENTS

In the Office action of November 3, 2006 objection was taken to the numbering of the claims and claims 1-26 were rejected.

The claims were objected to because a claim numbered 23 was not included in the application as filed. The applicants request cancellation of claims 24-26 and addition of new claims 27-29, preserving the original numbering of claims. The applicants request withdrawal of the objection.

Claims 11 and 17 stand rejected under 35 U.S.C. §112, second paragraph, because the claims contain the trademark/trade name ASTM-75, ASTM-F-75 and ASTM-799. According to the office action, claims 11 and 17 are not in compliance with the requirements of 35 U.S.C. 112, second paragraph, because the trademarks ASTM-F-75, etc. are used to identity/describe a cobalt chromium alloy. The applicants respectfully submit that the presence of a trademark or trade name in a claim is not *per se* improper under 35 U.S.C. 112, second paragraph, (MPEP 2173.05(u)) and the trademarks/trade names ASTM, ASTM-F-75, etc. are correctly used in claims 11 and 17 to identify the source of a standard material specification. The standard material specification is widely used in commerce to definitively describe an alloy of cobalt and chromium that is useful for the construction of orthopedic implants. The applicants respectfully submit that the trademarks/trade names are not used in claims 11 and 17 to identify or describe a cobalt-chromium alloy or the source of a cobalt-chromium alloy and that the claims are definitive of what the public is not free to use *Ex parte Simpson*, 218 USPQ 1020, 1022 (Bd. App. 1982). The applicants request amendment of claims 11 and 17 to correct a typographical error in the reference to the ASTM-F-75 specification. The applicants respectfully submit that claims 11 and 17 are definite; comply with 35 U.S.C. 112, second paragraph, and request withdrawal of the rejection.

Claim 6 stands rejected under 35 U.S.C. 112, second paragraph, because according to the office action, it is not clear how the polymer is structurally related to the article. The applicants request amendment of claim 6 to recite a first body that includes a first surface comprising one of a metal, a polymer, a ceramic or bone; and a second body that includes a second surface that is in contact with the first surface of the first body and movable relative

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thereto. The applicants respectfully request withdrawal of the rejection.

Claims 1-22 and 24-26 stand rejected under 35 U.S.C. 102(b) as anticipated by Shetty. U.S. Patent No. 5,308,412 (Shetty). With regard to claims 1, 10, 11, 16 and 17, the office action asserts that Shetty discloses a method of surface hardening an implant device of a cobalt-chromium alloy in which a layer of chromium nitride is attached to the surface (col. 2, line(s) 64 - col. 3, line(s) 7 and col. 7, line(s) 55-65) by a process that utilizes nitrogen gas with pressure applied at a temperature of 500-2400° F to form a CrN layer as the surface layer (col. 5, line(s) 51-60 and claim 1) (col. 2, line(s) 64 - col. 3, line(s) 5) and (col. 7, line(s) 55-65). Shetty, col. 2, line(s) 65 - col. 3, line(s) 3, referred to in the office action, indicates that the implant includes "an outer chromium nitride hardened surface layer." The applicants respectfully submit, however, that this indicates only that the surface layer includes chromium nitride and that chromium nitride is, at least, partially responsible for the hardening of the surface, but does not disclose or suggest that the surface layer is a layer of chromium nitride, as suggested in the office action, or a layer substantially comprising chromium nitride and such an interpretation is at odds with the remainder of Shetty's disclosure. The office action also asserts that col. 5, line(s) 51-60, and claim 1 of Shetty disclose that a chromium nitride surface layer is formed by the process, but the applicants submit that col. 5, line(s) 51-60 is silent about a surface layer and claim 1 states only that the outer surface layer of the implant is hardened. Moreover, the office action asserts that col. 2, line(s) 18-30 of Shetty describes a process that forms a CrN layer as the surface layer, but the applicants respectfully submit that the cited portion of Shetty states that the process "prevents the formation of a substantial CrN layer on the surface" which, according Shetty would be undesirable. The applicants submit that the process of Shetty produces a surface layer that includes chromium nitride, chromium oxide and chromium carbide (col. 7, line(s) 60-65 and claim 5) and that chromium nitride comprises only a minor fraction of the surface layer (see claim 4 which indicates that peak nitrogen concentration in the "hardened surface region" ranges between about 5 and about 50 atomic percent). The applicants respectfully submit that Shetty does not disclose or suggest a medical device having a surface layer comprising substantially chromium nitride and, further, Shetty teaches that such a surface layer would be undesirable and that the process disclosed therein prevents the formation of such a surface layer. The applicants request withdrawal of the rejection of claims 1, 6, 10, 11, 16 and 17.

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With regard to claims 2, 3, 7, 8, 13 and 14, the applicants respectfully submit that the claims are dependent respectively from one of claims 1, 6 or 12, or a claim dependent from one of claims 1, 6, or 12, and inherit the limitations of the claim(s) from which each respectively depends. The applicant submits that since claims 1, 6, and 12 are not anticipated by Shetty, for the reasons stated above, claims 2, 3, 7, 8, 13 and 14 are not anticipated by Shetty.

With regard to claims 4, 9 and 15, the office action asserts that Shetty teaches a similar method of producing a CrN layer but does not specifically teach the formation of a transition layer being disposed on the CrN layer after the heat treatment. However, according to the office action, Shetty is considered to teach forming a transition layer that is thinner than the surface layer because if the claimed products are identical or substantially identical in structure to the prior art products or are produced by an identical or substantially identical process, a prima facie case for anticipation or obviousness will be considered to have been established. The applicants respectfully submit that neither the process nor the products of Shetty are substantially identical to the applicants' process or the products produced by the applicants' process. The following table summarizes characteristics of the two processes:

	Shetty	Application
Reaction Gas	99.998% Nitrogen (col. 5, line. 10)	5-10% Nitrogen, 90-95% Hydrogen [0030]
Pressure	+ 1-2 psig. (col. 5, line. 21)	< 0 psig. (partial vacuum) [0030]
Temperature	500-2400°F (col. 3, line. 10)	250 - 1000°C (480 - 1800°F) [0024]
Voltage	N/A	450 – 550v. pulsed [0029]

The applicants respectfully submit that there is substantially no similarity between the two processes and, as stated above with regard to claims 1, 10 etc., the products produced by the two processes are distinctly different. Moreover, the applicants respectfully submit that Shetty does teach a transition layer between a surface layer which is defined by a surface of the device and the substrate material but Shetty teaches that the diffusion or transition layer has a depth which is greater than the depth of the surface layer (col. 3, line(s) 3-5) while claims 4, 9 and 15 claim a device including a transition layer that is thinner than the surface layer. The applicants respectfully submit that neither the process nor the product of Shetty is substantially identical or even similar to the applicants' process or product and request withdrawal of the rejection of claims 4, 9 and 15.

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With regard to claim 5, the applicants respectfully submit that the claim is dependent from claim 1 and inherits all of the limitation of the claim from which it depends. Since claim 1 is not anticipated by Shetty, for the reasons set out above, the applicants submit claim 5 is not anticipated. The applicants request withdrawal of the rejection.

With regard to claim 6, the applicants submit that for the reasons set out above with regard to claim 1, Shetty does not teach a medical device having a surface layer comprising substantially chromium nitride and, therefore, claim 6 is not anticipated. The applicants request withdrawal of the rejection.

With regard to claims 12, 18, 19, 20, 21, 22, 24, and 26, the office action asserts that if the product in a product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. The applicants respectfully submit that Shetty, as set out with regard to claims 1, 10, 11, 16 and 17, does not disclose an implant having a surface layer comprising substantially chromium nitride and teaches a process that prevents formation of such surface layer because, in the opinion of Shetty, a surface layer of chromium nitride is undesirable. The applicants respectfully submit that the medical devices of claim 12 and dependent claims 18, 19, 20, 21, 22, 24, and 26 are neither disclosed or suggested by Shetty and, according to Shetty, are not produced by the process disclosed therein which differs substantially from the applicants process. The applicants request withdrawal of the rejection of claims 12, 18, 19, 20, 21, 22, 24, and 26.

With regard to claim 25, the office action asserts that Shetty teaches a method of hardening a surface of a cobalt chromium based implant device by attaching a layer of chromium nitride to the surface of the metal alloy (col.2, line(s) 64-70 - col.3, line(s) 1-5) having a thickness as little as 0.2 microns (Table II) to less than 100 microns. The applicants respectfully submit, as set out with regard to claims 1, 10, 11, 16 and 17, that Shetty does not disclose an implant having a surface layer that comprises substantially chromium nitride of any depth. The applicants request withdrawal of the rejection.

Claims 2, 3, 7, 8, 13 and 14 stand rejected under 35 U.S.C. 103(a) as unpatentable over Shetty. According to the office action, Shetty teaches a layer of CrN having a thickness between 0.2 and 100 microns because it would have been obvious to select a surface layer having a thickness within the range specified by Shetty. However, the applicants submit that claims 1, 6

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and 12 are neither anticipated nor obvious from Shetty because Shetty does not disclose a medical device having a surface layer of any thickness that comprises substantially chromium nitride and teaches that such a surface layer is undesirable. Claims 2, 3, 7, 8, 13 and 14 are respectively dependent from one of claims 1, 6, and 12 and the applicants submit that since claims 1, 6, and 12 are neither anticipated nor obvious from Shetty, claims 2, 3, 7, 8, 13 and 14 are not obvious from Shetty. The applicants request withdrawal of the rejection.

This amendment is submitted with a request for extension of time and the applicants provisionally petition for an additional extension of time, if necessary. The applicants assert that no additional claim fees are due. However, the Commissioner is hereby authorized to charge any required additional fee for any additional extension of time or additional claims to the Deposit Account referred to in the enclosed petition for extension of time.

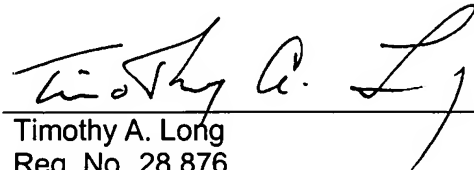
The applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Examiner believes that for any reason direct contact with applicants' attorney would

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advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Dated: _____

Timothy A. Long